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EP 0 320 080 B1

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**Description**

This invention relates to a new and improved device, for biostimulation of tissue with low-power radiation, preferably substantially monochromatic radiation, having a plurality of wavelengths and having 5 significant power densities over a treatment area.

For many years, high-powered, highly focused lasers have been widely used to cut and destroy tissue in many surgical techniques. More recently, low-powered lasers, less sharply focussed, which do not sever or destroy tissue have been found or are thought to effect numerous metabolic processes, including cell division, cyclic-AMP metabolism, oxidative phosphorylation, hemoglobin, collagen and other protein synthesis, leukocyte activity, tumor growth, production of macrophage cells and wound healing. See, for example, Karu and Letokhov "Biological Action of Low-Intensity Monochromatic Light in the Visible Range" in Laser Photobiology and Photomedicine, ed. Martellucci, p. 57-66 (Plenum Press 1985); Passarella, et al., "Certain Aspects of Helium-Neon Laser Irradiation on Biological Systems in Vitro" in Laser Photobiology and Photomedicine, ed. Martellucci p. 67-74 (Plenum Press 1985); see generally, Parrish, "Photomedicine: 10 Potentials for Lasers. An Overview," in Lasers in Photomedicine and Photobiology, ed. Pratesi, p. 2-22 (Springer 1980); Giese, "Basic Photobiology and Open Problems" in Lasers in Photomedicine and Photobiology, ed. Pratesi, p. 26-39 (Springer 1980); Jori, "The Molecular Biology of Photodynamic Action" in Lasers in Photomedicine and Photobiology, ed. Pratesi, p. 58-66 (Springer 1980). Although the precise mechanism for these effects is not fully understood, it is believed to be tied to the activity of specific 15 wavelengths of radiation in or near the range of visible light. Infrared laser radiation has been shown to increase ATP concentration and ATPase activity in living tissues. Bolognani, et al., "Effects of GaAs Pulsed Lasers on ATP Concentration and ATPase Activity In Vitro and In Vivo", International Cong. on Lasers in Medicine and Surgery, p. 47 (1985).

Radiation sources operating in or near the range of visible light, including lasers, emit photons which 20 may interact with biological molecules to produce photochemical reactions and subsequent biologic effects. Photochemical and photobiological events at the atomic level depend upon the wavelength of radiation used to cause such events and occur without regard to the source of photons. However, the molecular effects, kinetics and products can be quantitatively and qualitatively altered one or more by other properties of 25 radiation sources, e.g., monochromaticity, coherence and high power and energy density.

Most forms of photoexcitation are "quantum specific," i.e., excitation will only occur if a bundle of energy of a precise quantity is present to excite a given molecule or part of a molecule. A photon has energy E according to the formula:

$$35 \quad E = h \times f = \frac{h \times c}{wavelength}$$

where f is frequency, h is Planck's constant and c is the speed of light. If a photon having a quantum of too 40 little or too much energy is directed at a target molecule, it may not be absorbed; the photon must be of an exact energy to have an effect.

Only radiation which is absorbed has photochemical effects. X-rays, gamma rays and other absorbed high-energy photons affect human tissues by relatively indiscriminate ionization of molecules. The ionized molecules are highly reactive and covalent bonds may be broken or formed. Infrared photons excite 45 specific vibrational or rotational modes in specific target molecules. The quantum of energy required to produce vibrational or rotational excitation is dependant on the character (e.g., double bond vs. ring structure) and location (e.g., near an electrophilic group vs. near a nucleophilic group) of the molecule. While it is believed that infrared photons may affect specific biological processes or transformations, the most significant biological effect of these wavelengths is probably the heating caused by dissipation of the 50 vibrational and rotational energy, which can significantly effect biological reactions in the vicinity of the dissipating molecule. The energy of photons in the ultraviolet and visible wavelengths causes electronic excitation of specific chromophores (i.e., molecules that absorb a photon of a given wavelength and use the energy to cause transition of an electron to a higher energy state). The decay of these stimulated molecules can then lead to specific reactions, including emission of a new photon, transfer of an electron or dissipation 55 of heat.

In the past it has been difficult, however, to expose more than the first few layers of human skin or tissue to visible (400-700 nm) and ultraviolet (200-400 nm) radiation. Pigments and other molecules in the outer layers of skin are known to absorb the majority of visible and ultraviolet radiation, as shown in Figs. 1-

3. Table 1 summarizes the approximate penetration of various wavelengths of radiation into the skin.

TABLE 1

| Approximate depth of penetration of optical radiation in Fair Caucasian Skin to a value of $I/e$ (37%) of the incident energy density |                |           |
|---|----------------|-----------|
|   | Wavelength, nm | Depth, nm |
| 10  | 250            | 2         |
|   | 280            | 1.5       |
|   | 300            | 6         |
|   | 350            | 60        |
|   | 400            | 90        |
|   | 450            | 150       |
| 15  | 500            | 230       |
|   | 600            | 550       |
|   | 700            | 750       |
|   | 800            | 1200      |
|   | 1000           | 1600      |
|   | 1200           | 2200      |

As shown in Fig. 3, no ultraviolet radiation and approximately only 5% of most visible radiation penetrates to the subcutaneous layer of the skin. As a result, applying visible and ultraviolet radiation to the skin has little or no effect upon target molecules in lower layers that would become stimulated if exposed to those wavelengths of radiation.

While higher powered radiation sources can deliver greater energy to deeper layers, it is undesirable to directly expose tissue to large amounts of ultraviolet radiation due to the adverse effects of such radiation upon some molecules and cellular functions, e.g., DNA can be "mutated" by ultraviolet radiation.

It would therefore be desirable to provide a safe device for biostimulation of tissue that will stimulate biological processes affected by visible red and infrared radiation and also stimulate biological processes in lower layers of tissue that are affected by ultraviolet and visible radiation and would normally be inaccessible to radiation applied to the surface of the tissue because of the absorption of visible and ultraviolet radiation by skin pigments and other molecules. In specification WO 87/04632 (Carl Zeiss) relating to the therapeutic irradiation of organic tissue, two beams respectively from two different lasers are directed along the same path. The first is an infra-red beam that acts as a biostimulator and the second simply provides light on the surface being irradiated because the infra-red beam is invisible. Specification US 4646743 (Parris) describes the use of diode lasers that produce single frequency infra-red radiation for the treatment of animals. The beams from the lasers are either widely spaced and parallel or divergent. European specification EP-A-0266238 (Kureha Kagaku Kogyo) which is an intermediate document relates to the treatment of a cancerous lesion after treatment with a photosensitive substance by two laser diodes having a wavelength of 630 nm and 690 nm for irradiating the lesion part simultaneously with the beams from these two kinds of light emitting diodes such that the photochemical reaction of the photosensitive substance is enhanced. Clearly these prior proposals do not anticipate or even suggest the solution of the aim of the present invention which is to provide a device for the delivery of significant amounts of low-power substantially monochromatic radiation to points at subcutaneous tissues where a single light source has proved ineffective because of its inability safely to penetrate the outer layers of the tissue.

According to the invention, a unitary device for biostimulation of tissue comprising an array of radiation sources mounted in a substantially flat plane at fixed distances from one another is characterised in that each said source consists of a substantially monochromatic radiation source chosen to provide visible or infrared radiation of a selected wavelength, the sources being mounted in a unit to be positioned in relation to the tissue, and that at least two of such sources are chosen and positioned to provide different wavelengths of sufficient intensity to penetrate a patient's skin at separate locations while converging to a subcutaneous point with sufficient power to trigger a biostimulating effect at such point while the device is presented to the skin, said radiation sources being operable to deliver wavelengths chosen to be synergistic in respect of one another and comprising at least one diode providing a first said radiation source having a wavelength equal to or greater than 650 nm and less than 800 nm and at least one diode providing a second said radiation source having a wavelength greater than or equal to 800 nm and less than or equal to

1500 nm.

According to another aspect of the invention, a unitary device for biostimulation of tissue comprising an array of radiation sources mounted in a substantially flat plane of fixed distances from one another is characterised in that each said source consists of a substantially monochromatic radiation source chosen to provide visible or infrared radiation of a selected wavelength, the sources being mounted in a unit to be positioned in relation to the tissue, and that at least two of such sources are chosen and positioned to provide different wavelengths of sufficient intensity to penetrate a patient's skin at separate locations while converging to a subcutaneous point with sufficient power to trigger a biostimulating effect at such point while the device is presented to the skin, said radiation sources being operable to deliver wavelengths chosen to be synergic in respect of one another and comprising at least one such radiation source providing a first wavelength less than 830 nm, at least one such radiation source providing a second wavelength greater than or equal to 830 nm and less than 900 nm and at least one such radiation source providing a third wavelength greater than or equal to 900 nm.

**15 BRIEF DESCRIPTION OF THE FIGURES**

Fig. 1 is a graph summarizing the ultraviolet absorption spectra of major epidermal chromophores: DOPA-melanin, 1.5 mg% in H<sub>2</sub>O; urocanic acid, 10<sup>-4</sup> M in H<sub>2</sub>O; calf thymus DNA, 10 mg% in H<sub>2</sub>O (pH 4.5); typtophan 2 x 10<sup>-4</sup> M pH 7; tyrosine, 2 x 10<sup>-4</sup> (pH 7). [From Pratesi and Sacchi, Eds., Lasers in Photomedicine and Photobiology, p. 165 (Springer 1980)];

Fig. 2 is a graph summarizing the visible light absorption spectra of major human skin pigments. Parentheses indicate solvents used. [From Pratesi and Sacchi, Eds., Lasers in Photomedicine and Photobiology, p 172 (Springer 1980)];

Fig. 3 is a pictorial and graphic representation of the relative penetration of various radiation wavelengths into human skin. [From D Slimey and M Wolbarsht, Safety with Lasers and other Optical Sources (1980)];

Fig. 4 is a function block diagram of the device and system of the present invention;

Fig. 5 is a side view of a cluster probe or radiation source array used in the present invention;

Fig. 6 is a plan view of a radiation source array used in the present invention.

Fig. 7 is a plan view of another radiation source array comprising an alternative embodiment of the present invention.

Fig. 8 is a plan view of another radiation source array comprising an alternative embodiment of the present invention.

Fig. 9 is a simplified schematic view of the radiation beams of three diodes as used in the present invention impinging on a treatment tissue target.

**DETAILED DESCRIPTION OF THE INVENTION**

**A. System Overview.**

The block diagram of Fig. 4 shows the overall structure of the device and system of the present invention. A control unit 20 contains both controls and displays to read out control settings and measured values. To this control unit 20 a single beam probe 30 and a cluster probe 60 may be connected at plug-in connections 32 and 62, respectively. Central to the control unit 20 are a beam power supply 40 and, connected thereto a beam control logic unit 70. The beam power supply has two output lines 43 and 46. Output line 46 leads to plug-in connection 62 for the cluster probe 60. Output line 43 leads to plug-in connection 32 for single beam probe 30.

Beam power control 41 is connected to beam power supply 40 to permit setting of the beam power level. Beam power meter 42 is connected to the beam power supply 40 to show the power level being delivered.

To provide radiation beams modulated in pulses of various frequencies, a beam oscillator 45 is connected to the beam power supply 40. The beam oscillator 45 is controlled by an oscillator frequency control 47 connected to the beam oscillator 45. A frequency meter 48 connected to the oscillator frequency control 47 provides display of the selected beam modulation frequency. If pulse duration modulation is desired as a further form of modulation, this can be accomplished by additional refinements of the beam oscillator 45 and its corresponding oscillator frequency control 47.

The beam control logic unit 70 is, as previously noted, connected to the beam power supply 40. An indicator light 71 associated with the unit shows when the beam power is on. This is useful because the

beam wavelengths being used may not be visible and treatment time, as well as power, is an important variable ( $E = P \times T$ ). As a further check that the unit is functioning, the invention provides a beam output photosensor 50 connected to the beam control logic unit 70 described below). This photosensor 50 is sensitive to the frequencies of radiation produced by the unit and provides a signal when it receives radiation. To aid control of treatment time, a down-counting program timer 72 with a display 73 that follows the down count is connected to the beam control logic unit 70. A further display 75, also connected to the beam control logic unit 70, provides a display of total beam on-time (in minutes).

For some uses of the invention, it is desirable to locate body points of high skin conductivity. (These usually correspond to pain trigger points of inflammatory areas, as increased temperatures will raise skin conductivity.) The present invention does this with a skin conductivity measuring module 75 connected to beam control logic unit 70, with associated display 76. This module 75 delivers a small current (microamps) via a lead 77 connected to an electrode 79 held in the hand of a patient. The single beam probe 30 is used to form a return path from a selected skin location, utilizing lead 78 as a return current path (from plug-in connection 32) to the skin conductivity measuring module 75. If desired, the skin conductivity measurement can be used as a trigger for the beam control logic unit 70; that is, the beam control logic unit 70 can be set to enable a beam only when a preselected skin conductivity level is present. When this level is chosen to be very low, the beam is enabled whenever the return path probe is in contact with a skin area to be treated.

The present invention utilizes, as noted above, radiation in or near the infrared spectrum (below 1500 nm) and the visible light spectrum (above 650 nm). For convenience in the following, the radiation comprising the beams produced by the present invention may be referred to as "light", although it may be in the visible or ultraviolet spectra or in other nearby spectra.

The single beam probe 30 of the present invention is shaped like a fat pencil (Fig. 4). It emits radiation of a single frequency and is therefore of limited interest in connection with the present invention. The gravamen of the invention is use of multiple radiation sources of multiple frequencies. This radiation is emitted by the multiple radiation sources contained in cluster probes 60 used with the present invention.

Fig. 5 shows a side view of a cluster probe 60, having a thin cylindrical handle 61 and a thicker cylindrical head 62. Figs. 6 through 8 show three patterns of radiation sources that can be contained within the cylindrical head 62. The radiation is emitted from a plane very near one end-face of the cylinder 62. Figs. 6-8 show head-on views of several end-faces. As will be described below, the end-faces involve various configurations of radiation sources. Each of these configurations provides a different mix of radiation source frequencies and a somewhat different geometric configuration. These configurations accordingly produce different "mixtures" of radiation frequencies in the target tissue and different power densities.

The sources of light or radiation in each of the cluster probes 60 in Figs. 6-8, showing particular forms of radiation arrays, are semiconductor light emitting devices, e.g., light emitting diodes (LED'S). Two particular types of LED'S have been found most useful for purposes of the present invention: laser diodes and superluminous diodes. Laser diodes produce a beam of light or radiation that is essentially monochromatic, is sharply collimated and is coherent. That is, they produce light almost exclusively at one frequency (unless they are multi-mode type lasers) and the light beam has a small angle of divergence. Superluminous diodes are also used. These are similar but lack the coherence and the sharply monochromatic characteristics of laser diodes; yet they produce highly directional light that is also limited in its frequency range.

A number of commercially available semiconductor laser diodes exist. Typical of these are those described in "Optoelectronic Devices Data Book" published by Hitachi, Ltd. (September, 1984).

It has been found, however, that semiconductor laser diodes having somewhat higher power outputs and narrower beam divergence and spectral widths than the most widely manufactured components are also available and may enhance the advantages of the present invention. Not all frequencies are available in the range from ultraviolet through visible to infrared radiation. But enough are available that some selection among frequencies can be made. Among low power lasers suitable for the present invention, the laser power rating (continuous power) of individual diodes is generally in the range from 5-500 milliwatts (mW). Laser diodes are available with continuous wave emission capability and as devices that must be pulsed. The following laser diode specifications have been found useful for the present invention:

1. Double Heterostructure Continuous Wave Laser Diode GaAlAs

Wavelength: 750, 780, 800, 810, 820, 830, 850nm

55 Peak Power Output: 5mW - 500 mW (Class 3B)

Beam Divergence: 60° parallel, 12° perpendicular (typical, variable according to manufacturing method)

Polarisation: Linear 90-100%

Spectral Width: 0.02mm-1.0mm

2. Single Heterostructure Pulsed Laser Diode GaAs

Wavelength: 904nm

Peak Power Output: 70W

Avg. Power: 0.15-15mW (frequency dependent)

5 Max. Pulse Duration: 200 microsecs.

Beam Divergence: 6°-15° parallel, 15°-30° perpendicular

Spectral Width: less than 3.5mm

3. Double Heterostructure Pulsed Laser Diode GaAs/GaAlAs Wavelength: 850-904nm

Peak Power: 325mW

10 Average Power: 40-80mW

Fixed Duty Factor ( $T_w \times F_n$ ): 15%;  $f = 300\text{KHz}$ ,  $T_w = 500$  microsecs.

Beam Divergence: 6°-15° parallel, 15°-30° perpendicular

Spectral Width: 2-3mm

15 As best seen in Fig. 6, the preferred embodiment of the cluster probe 60 of the present invention comprises an array 80 of five 660 nm superluminous diodes 166, one 820 nm laser diode 182, ten 880 nm superluminous or laser diodes 188 and five 950 superluminous diodes 195. The diodes are arranged in a planar array such that the 820 nm diode 182 is positioned in the center of the array, five of the ten 880 nm diodes 188 are evenly positioned about the circumference of a circle of about 9.5 mm radius from the center of the array, the five 660 nm diodes 166 are evenly positioned about the circumference of a circle of about 18 mm radius from the center of the array such that a radial line from the center of the array to each 660 nm diode 166 bisects the arc between two of the innermost 880 nm diodes 188, the 950 nm diodes 195 are evenly positioned about the circumference of a circle of about 27 mm radius from the center of the array such that a radial line from the center of the array to each 950 nm diode 195 passes through the center of one of the innermost 880 nm diodes 188, and the remaining five 880 nm diodes 188 are evenly 20 positioned about the circumference of a circle of about 27 mm radius from the center of the array such that a radial line from the center of the array to each outer 880 nm diode 188 passes through the center of one of the 660 nm diodes 166.

25 In an alternative embodiment shown in Fig. 7, the 820 nm diode, 182 is positioned in the center of the array 90, ten 880 nm diodes 188 are evenly positioned about the circumference of a circle of about 10.5 mm radius from the center of the array, and five 660 nm diodes 166 and five 950 nm diodes 195 are alternately positioned and evenly spaced about the circumference of a circle of about 17 mm radius from the center of the array, such that a radial line from the center of the array to each 660 nm or 950 nm diode, 166, 195 respectively, bisects the arc between two of the 880 nm diodes 188.

30 Another alternative embodiment of the cluster probe 60 of the present invention, shown in Fig. 8, comprises an array 100 of ten 660 nm superluminous diodes 166, one 820 nm laser diode 182, ten 880 nm superluminous or laser diodes 188, and ten 950 nm superluminous diodes 195. The diodes are arranged in a planar array such that the single 820 nm diode 182 is positioned in the center of the array, ten 880 nm diodes 188 are evenly positioned about the circumference of a circle of about 9.5 mm radius from the center of the array, ten 660 nm diodes 166 are evenly positioned about the circumference of a circle of about 18 mm radius from the center of the array such that a radial line from the center of the array to each 660 nm diode 166 bisects the arc between two of the 880 nm diodes 188, and ten 950 nm diodes 195 are evenly positioned about the circumference of a circle of 27 mm radius from the center of the array, such 35 that a radial line from the center of the array to each 950 nm diode 195 passes through the center of one of the 880 nm diodes 188.

40

B. Theory of Operation

45 The diodes within the array of each embodiment are closely arranged such that although the radiation they produce is emitted in a narrow beam, their beams overlap a short distance away from the surface of the cluster probe 60. Thus, as can be seen in Fig. 9, two or more wavelengths of radiation from the array 60 simultaneously pass through some point in the tissue 100 being stimulated. In Fig. 9, the divergence of each radiation beam is schematically shown for three radiation sources 182, 188 and 195 assumed to lie along a single line. Radiation source 182 is assumed to have a beam divergence of six degrees, while radiation sources 188 and 195 are assumed to have beam divergence of 15 degrees. No other optical 50 effects such as reflection, refraction or scattering are assumed. Fig. 9 shows that the beams will begin to overlap after they have traveled a few centimeters from the face of the cluster array 60. Obviously, overlap occurs even sooner when the diodes are more closely spaced.

When tissue is stimulated with these arrays of radiation sources, a cumulative, and sometimes synergistic, effect is believed to occur, which is not seen when a single wavelength is used. It has been proposed that this effect is due, in part, to the "mixing" of photons of different wavelengths which results in three types of "two-photon events". In the first type, two different adjacent molecules are excited by different wavelength photons. In the second type, two different parts of the same molecule are excited by different wavelength photons. Both of these types of events produce excited states that would not be possible if the same molecules were stimulated with photons of only one wavelength. These "new" excited states may also make the molecule(s) involved more susceptible to certain types of decay, dissipation and reaction with each other or other unexcited molecules.

10 In the third type of two-photon event, a single electron is simultaneously excited by two coinciding photons of different wavelengths. The high density of photons produced by devices of small emitting surface area of the present invention enhances the probability of this type of two-photon event occurring. Assuming that all of the simultaneously-presented energy is absorbed by an electron, the resultant quantum of energy delivered by two photons is equivalent to that of a photon of a much smaller wavelength. For 15 example, for an 880 nm photon:

$$E_{880} = \frac{h \times c}{880 \text{ nm}}.$$

20

For an 820 nm photon:

$$E_{820} = \frac{h \times c}{820 \text{ nm}}.$$

25 Since the effective energy of both photons will be the sum of  $E_{880}$  and  $E_{820}$ :

$$30 E_{\text{effective}} = E_{880} + E_{820} = \frac{h \times c}{\text{effective wavelength}},$$

The effective wavelength is about one-half of the average of the two original wavelengths or, in this 35 example, approximately 425 nm. In effect, the target molecule is stimulated as if it had been hit with a single 425 nm photon.

The third type of two-photon event is especially significant because 425 nm is a wavelength that would normally be absorbed by skin pigments and would not penetrate very deeply into the skin. By stimulating the tissue with photons at 880 nm and 820 nm the screening effect of the skin is avoided. In certain 40 preferred and alternative embodiments diodes of four wavelengths are used, thus creating ten different two-wavelength combinations, resulting in ten effective wavelengths during the third type of two-photon event. The effective wavelengths range from 330 nm to 475 nm which approximately corresponds to the range of highest absorption by skin pigments as shown in Fig. 2.

As noted above, an array of radiation sources as used in the present invention may be comprised of 45 laser, superluminous and similar light-emitting diodes. These types of diodes are all substantially monochromatic non-gaseous radiation sources. Continuous wave diodes are preferable, because they have a higher average available power than pulsed diodes. Appropriate diodes are available from several suppliers at wavelengths of 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm, 820 nm, 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, 880 nm, 900 nm, 904 nm, 1100 nm, 1300 nm and 1500 nm. These radiation sources 50 are "substantially monochromatic," as that term is used throughout this specification and the appended claims, in that, in addition to emitting light or radiation at substantially one "main" wavelength, they also emit a significantly smaller amount of radiation at other wavelengths which are close, but not identical, to the "main" wavelength. A laser diode will emit at a "main" wavelength and a few peripheral wavelengths (corresponding to multiple resonances or off-axis modes) characterized by distinct narrow spikes in its 55 wavelength spectrum. A superluminous or other light-emitting diodes will emit at a "main" wavelength that is at the peak of a somewhat broader continuous band of wavelengths in a wavelength spectrum. By convention, the "main" wavelength is used to identify the diode (e.g., a "800 nm diode" will emit at a "main" wavelength of 800 nm and at some other peripheral wavelengths characteristic of the material from

which the diode is made). It should be noted that the number of combinations of two wavelengths leading to possible two-photon events is increased dramatically by the existence of peripheral wavelengths associated with the "main" wavelength of each type of diode. The slight variations in wavelength can lead to virtually hundreds of two-wavelength combinations and, as a result, hundreds of effective wavelengths in the visible and ultraviolet spectra.

5 A further object of the present invention according to a preferred embodiment is the delivery of significant amounts of low-power radiation to deeper tissues. For this reason, the radiation sources, while low-powered, are relatively tightly-clustered. For the arrays shown in Figs. 6-8, the average power density at the plane of the array is in the range from about 10mW/cm<sup>2</sup> to about 40 mW/cm<sup>2</sup>. Due to beam divergence, 10 absorption, reflection, refraction, scattering and other similar effects, the average power density decreases with distance from the plane of the array either through air or into tissue. It should be noted, however, that due to the small radiation surface areas of some laser diodes, certain small areas near the plane of the array or at the surface of the treated tissue (when the cluster probe 60 is placed immediately adjacent the tissue) may have a power density of at least 120 mW/cm<sup>2</sup>. Should it be found that higher energy densities 15 yield enhanced biostimulative effects without undesirable side effects, even higher powered diodes and/or somewhat more densely clustered diodes can be utilized. Of course, the energy delivered to a given area of tissue is also a function of time of exposure. Accordingly, it is also useful to speak of an energy density provided per unit area, defined as the power density multiplied by the exposure time. By this formula, a sixty second exposure of tissue with a minimum power density of 120mW/cm<sup>2</sup> (which might be found to be 20 a minimum exposure for some significant therapeutic result) could be described as of minimum treatment energy density of 7.2 Joules/cm<sup>2</sup>.

25 In the preferred and alternative embodiments of present invention, the radiation sources can be modulated in pulses of different frequencies ranging from 2.28 Hz to 400 kHz, including 2.28 Hz, 4.56 Hz, 9.12 Hz, 16 Hz, 18.24 Hz, 36.48 Hz, 73 Hz, 146 Hz, 292 Hz, 700 Hz, 1000 Hz, 5 kHz and 300 kHz. This is done by means of the oscillator frequency control 47 mentioned above. Other frequencies could obviously be selected. As mentioned above, the beam oscillator 45 and its frequency control 47 can also provide 30 pulse duration modulation for continuous wave radiation sources. Thus, for the same frequency a higher average power can be obtained according to the formula:  $P$  (average) =  $P$  (peak) x Pulse duration x Frequency.

30

## 2. Method of Treatment

The method involves exposing the tissue to a plurality of radiation sources of different wavelengths. More generally, the method of treatment involves the simultaneous exposure of the tissue to at least three 35 different wavelengths of radiation. Any embodiment of the device of the present invention, including but not limited to those previously described, can be used to perform this method of treatment. The array of radiation sources is preferably placed directly adjacent to or on the skin such that the plane of the radiation sources is close to or comes in contact with the outermost layer of skin. Because oils and other substances on the surface of the skin may cause absorption, refraction, reflection and/or diffraction of some 40 wavelengths of radiation and thereby decrease radiation penetration, for effectiveness these should be removed before treatment.

Devices of the present invention have been used to treat various conditions in clinical settings. The results of those clinical applications as reported by several medical doctors and physiotherapists in the United Kingdom are summarized in the following examples.

45

### Example 1

A patient had a thirteen year history of extreme pain in the right big toe after engaging in sports activities. Upon examination, the patient was found to have a congenital Hallux Valgus or chronic "bunion". 50 The sore toe was treated with a multi-diode biostimulation device of the present invention (660 nm, 820nm 880 nm, 950 nm) for a period of ten minutes. The patient experienced immediate relief of all pain and was able to engage in sports activities the day after treatment.

55

### Example 2

A patient experienced post plaster pain for two weeks following an operation for Hallux Valgus on the left foot. Examination revealed pitting edema of the forefoot, slight swelling of the ankle and limited movement of the foot. The patient was treated daily for five minutes with a multi-diode biostimulation device

of the present invention (660 nm, 820 nm, 880 nm, 950 nm). Treatment continued for five days. Swelling decreased after each treatment. After the third treatment, the foot was pain free, but still slightly swollen. Upon completion of treatment, all symptoms had been relieved.

5 Example 3

A 24 year-old patient experienced pain after surgery to repair a ruptured left anterior cruciate ligament. The patient was treated twice daily with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 4 minutes, 30 seconds. After treatment, the patient was pain 10 free and showed signs of good tissue repair.

Example 4

A 38 year-old patient had experienced chronic fibrositis in the neck for 18 years. The patient was 15 treated daily for two days with a 21 diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 pm) for a period of 4 minutes, 30 seconds. Each treatment was followed by treatment by treatment with a 15 mW 850 nm single diode probe for two minutes. After treatment, the patient experienced 98% pain relief.

20 Example 5

A 35 year-old patient had experienced muscle spasms in the lower back. The patient was treated twice in a single day with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 4 minutes, 30 seconds. After treatment, the patient experienced total pain relief.

25 Example 6

A 33 year-old patient had experienced pain in the head of his fibula secondary to a knee injury in which the patient sustained a torn medial meniscus and ruptured anterior cruciate. The meniscus had been 30 removed. The pain radiated down the leg and was associated with limitation of knee flexion. The patient was treated six times with a 660 nm single diode probe for a period of 4 minutes followed by treatment with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 2 minutes. Laser treatment was used in conjunction with mobilizations. After treatment, the patient experienced relief of virtually all pain and regained full range of knee flexion.

35 Example 7

A 21 year-old patient had experienced an inflamed gluteal bursa. The patient was treated three times with a 31 diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm). After 40 treatment, the patient showed no further pain and no reoccurrence.

Example 8

A 35 year-old patient had experienced a non-healing skin ulcer for 3 years following a motorcycle 45 accident. The patient was treated 10 times with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm). After treatment, the tissue showed increased granulation (++) and the ulcer had decreased in size and looked healthier.

Example 9

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A 70 year old patient had experienced a diabetic ulcer following an above-knee amputation. The lateral third of the ulcer was treated with a 830 nm single diode probe and a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 90 seconds each. After treatment, increased healing, granulation and de-sloughing were observed.

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Preliminary indications are that the method and apparatus of the invention may be used widely for therapeutic purposes for example, to treat inflammations, wounds, burns, chronic ulcerations including diabetic ulcers, deficient circulation, pain, nerve degeneration, eczema, shingles, infection, scars, acne, bone fractures, muscle and ligament injuries, arthritis, osteo-arthritis, rheumatoidal arthritis, skin grafts, gingival

irritation, oral ulcers, dental pain and swelling, cellulitis, stretch marks, skin tone, alopecia areata, trigeminal neuralgia, herpes, zoster, sciatica, cervical erosions and other conditions.

Because of the nature of light and the optical properties of tissue, power density from a single light source obtained at subcutaneous tissue is attenuated. However, when multiple crossing or overlapping 5 beams of light are present, regions of added power density occur in the subcutaneous tissue which enable a therapeutic threshold to be achieved. The occurrence of these regions of added power density or "hot spots" enables sufficient energy density to be achieved within an acceptably short exposure time.

It has also been found as a result of laboratory research that certain cells, e.g. macrophages, when 10 exposed to light at particular wavelengths, release a number of wound factor chemicals which can assist in the repair of damaged tissue. For example, light at 820 (laser diode), 660, 870 nm (super luminous diode) released factors that helped the proliferation of fibroblasts significantly above control levels in in vitro culture. Monochromatic light at 880 nm (superluminous diode) released factors that inhibited fibroblast proliferation, which may be significant when uncontrollable fibroblast proliferation needs to be prevented e.g. to prevent keloids scar tissue formation after burns. It has been suggested that the protein coating of cells 15 may be involved and that different cells e.g. fibroblasts, T-cells, B-cells may each react at a different wavelength or set of wavelengths provided that there is more than a threshold energy density available and targeted to the cell. When a device according to the invention is used to irradiate tissue, cells along the path of the beams will react according to their sensitive wavelengths. Cells located at deeper strata may not respond to a single wavelength because of power density attenuation, but in the regions of the overlapping 20 beams or "hot spots" or similar or different wavelengths the energy density threshold can be achieved and a useful therapeutic result can be obtained. The possibility of 2-photon events and the effective new wavelengths created allows more kinds of cells to be targeted including possibly neural cells.

### Claims

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1. A unitary device for biostimulation of tissue comprising an array of radiation sources mounted in a substantially flat plane (80, 90, 100) at fixed distances from one another, each said source consists of a substantially monochromatic radiation source chosen to provide visible or infrared radiation of a selected wavelength, the sources being mounted in a unit to be positioned in relation to the tissue, and that at least two of such sources are chosen and positioned to provide different wavelengths of sufficient intensity to penetrate a patient's skin at separate locations while converging to a subcutaneous point with sufficient power to trigger a biostimulating effect at such point while the device is presented to the skin, said radiation sources (166, 182, 188, 195) being operable to deliver wavelengths chosen to be synergic in respect of one another and comprising at least one diode providing a first said radiation source having a wavelength equal to or greater than 650 nm and less than 800 nm and at least one diode providing a second said radiation source having a wavelength greater than or equal to 800 nm and less than or equal to 1500 nm.
2. A unitary device for biostimulation of tissue comprising an array of radiation sources mounted in a substantially flat plane of fixed distances from one another each said source consists of a substantially monochromatic radiation source chosen to provide visible or infrared radiation of a selected wavelength, the sources being mounted in a unit to be positioned in relation to the tissue, and that at least two of such sources are chosen and positioned to provide different wavelengths of sufficient intensity to penetrate a patient's skin at separate locations while converging to a subcutaneous point with sufficient power to trigger a biostimulating effect at such point while the device is presented to the skin, said radiation sources (166, 182, 188, 195) being operable to deliver wavelengths chosen to be synergic in respect of one another and comprising at least one such radiation source providing a first wavelength less than 830 nm, at least one such radiation source providing a second wavelength greater than or equal to 830 nm and less than 900 nm and at least one such radiation source providing a third wavelength greater than or equal to 900 nm.
3. The device for biostimulation of tissue of Claim 2, characterised in that:
  - (a) said radiation sources are selected from the group consisting of superluminous diodes and laser diodes; and/or
  - (b) said first wavelength is selected from the group consisting of 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm and 820 nm;
 said second wavelength is selected from the group consisting of 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, and 880 nm; and

5 said third wavelength is selected from the group consisting of 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm and 1500 nm; and/or

5 (c) said first wavelength is selected from the group consisting of 660 nm and 820 nm;  
said second wavelength is selected from the group consisting of 875 nm and 880 nm; and  
said third wavelength is 950 nm.

10 4. The device for biostimulation of tissue of Claim 3, characterised in that said radiation sources are modulated at pulse frequencies selected from within the range of 2.28 Hz to 400 kHz.

15 5. The device for biostimulation of tissue of Claim 4, characterised in that said pulse frequencies are selected from the group consisting of 2.28 Hz, 4.56 Hz, 9.12 Hz, 16 Hz, 18.24 Hz, 36.48 Hz, 73 Hz, 146 Hz, 292 Hz, 700 Hz, 1000 Hz, 5 kHz and 300 kHz.

20 6. The device for biostimulation of tissue of Claims 3, 4 or 5, characterised in that said array comprises:  
15 five 660 nm superluminous diodes (166);  
one 820 nm laser diode (182);  
ten 880 nm superluminous or laser diodes (188); and  
five 950 nm superluminous diodes (195).

25 7. The device for biostimulation of tissue of Claim 6, characterised in that:  
said 820 nm diode (182) is positioned in the center of said array;  
said 880 nm diodes (188) are evenly positioned about the circumference of a circle of 10.5 mm radius from the center of said array; and  
said 660 nm diodes (166) and 950 nm diodes (195) are alternately positioned and evenly spaced about the circumference of a circle of 17 mm radius from the center of said array such that a radial line from the center of said array to each of said 660 nm or 950 nm diodes bisects the arc between two of said 880 nm diodes.

30 8. The device for biostimulation of tissue of Claim 7, characterised in that:  
said 820 nm diode (182) is positioned in the center of said array;  
five of said 880 nm diodes (188) are evenly positioned about the circumference of a circle of 10.5 mm radius from the center of said array;  
said 660 nm diodes (166) are evenly positioned about the circumference of a circle of 17 mm radius from the center of said array such that a radial line from the center of said array to each of said 660 nm diodes bisects the arc between two of said 880 nm diodes in said first set;  
35 said 950 nm diodes (195) are evenly positioned about the circumference of a circle of 17 mm radius from the center of said array such that a radial line from the center of said array to each of said 950 nm diodes passes through the center of one of said 880 nm diodes in said first set; and  
the remaining five of said 880 nm diodes (188) are evenly positioned about the circumference of a circle of 27 mm radius from the center of said array such that a radial line from the center of said array to each of said 880 nm diodes passes through the center of one of said 660 nm diodes.

40 9. The device for biostimulation of tissue of Claim 3, characterised in that said array comprises:  
ten 660 nm superluminous diodes (166);  
one 820 pm laser diode (182);  
ten 880 nm superluminous or laser diodes (188); and  
ten 950 nm superluminous diodes (195).

45 10. The device for biostimulation of tissue of Claim 9, characterised in that:  
said 820 nm diode (820) is positioned in the center of said array;  
said 880 nm diodes (188) are evenly positioned about the circumference of a circle of 9.5 mm radius from the center of said array;  
said 660 nm diodes (166) are evenly positioned about the circumference of a circle of 18 mm radius from the center of said array such that a radial line from the center of said array to each of said 660 nm diodes bisects the arc between two of said 880 nm diodes; and  
55 said 950 nm diodes (195) are evenly positioned about the circumference of a circle of 27 mm radius from the center of said array such that a radial line from the center of said array to each of said 950 nm diodes passes through the center of one of said 880 nm diodes.

11. A device for biostimulation of tissue according to Claim 1, characterised in that said radiation sources comprise:
  - 5 at least one such radiation source providing a first wavelength less than 830 nm;
  - at least one such radiation source providing a second wavelength greater than or equal to 830 nm and less than 875 nm;
  - 10 at least one such radiation source providing a third wavelength greater than or equal to 875 nm and less than 900 nm; and
  - at least one such radiation source providing a fourth wavelength greater than or equal to 900 nm.
12. The device for biostimulation of tissue of Claim 11, wherein said radiation sources are selected from the group consisting of superluminous diodes and laser diodes.
13. The device for biostimulation of tissue of Claim 12, characterised in that:
  - 15 said first wavelength is selected from the group consisting of 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm and 820 nm;
  - said second wavelength is selected from the group consisting of 830 nm, 840 nm, 850 nm, 860 nm and 870 nm;
  - 20 said third wavelength is 880 nm; and
  - said fourth wavelength is selected from the group consisting of 900 nm, 904 nm, 950 nm, 110 nm, 1300 nm and 1500 nm.
14. A device for biostimulation of tissue according to Claim 1, characterised in that said radiation sources comprise:
  - 25 at least one diode providing a first wavelength less than 800 nm; and
  - at least one diode providing a second wavelength greater than or equal to 800 nm.
15. The device for biostimulation of tissue of Claim 14, characterised in that:
  - 30 said first wavelength is selected from the group consisting of 650 nm, 660 nm, 680 nm, 750 nm and 780 nm; and
  - said second wavelength is selected from the group consisting of 800 nm, 810 nm, 820 nm, 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, 880 nm, 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm and 1500 nm.
16. A device according to Claim 1, characterised in that said radiation sources (166, 182, 188, 195) are chosen to emit an average power density at said plane of at least 10 mW/cm<sup>2</sup>.
17. A device according to Claim 1, characterised in that said radiation sources (166, 182, 188, 195) are chosen to provide a power density of at least 120 mW/cm<sup>2</sup> at some point on the surface of the patient's skin.
18. A device according to Claim 1, characterised in that it is provided with
  - 40 (a) power-providing means (40) and means (47, 45) in communication with said power-providing means for modulating the output of said sources with pulses and varying the modulation pulse frequency of said radiation sources; and/or
  - (b) means (45) in communication with said power-providing means for varying the pulse duration of said radiation sources; and/or
  - (c) means (72, 70) in communication with said power-providing means for timing the period that power is provided to said radiation sources; and/or
  - (d) means in communication with said power-providing means (75, 70) for measuring the electrical conductivity of said tissue; and/or
  - (e) means (42) in communication with said array for measuring the optical power emitted by said radiation sources; and/or
  - (f) means (50) in communication with a beam control unit for detecting radiation from said radiation sources; and
- 55 indicator means (71) connected to said detecting means for indicating that radiation is being emitted from said radiation sources.

**Patentansprüche**

1. Als Einheit ausgebildetes Gerät zur Biostimulation von Gewebe, mit einer Anordnung von Strahlungsquellen, die im wesentlichen in einer Ebene (80, 90, 100) in festen Abständen voneinander angeordnet sind, wobei jede dieser Quellen aus einer im wesentlichen monochromatischen Strahlungsquelle besteht, die zum Liefern von sichtbarer oder infraroter Strahlung einer vorbestimmten Wellenlänge ausgewählt ist, wobei die Quellen in einer Einheit montiert sind, die in einer Beziehung zum Gewebe zu positionieren ist, und wobei wenigstens zwei dieser Quellen so ausgewählt und angeordnet sind, dass sie unterschiedliche Wellenlängen mit genügender Intensität liefern, um in die Haut eines Patienten an voneinander getrennten Stellen einzudringen und dabei an einer subkutanen Stelle mit genügend Leistung zu konvergieren, um an dieser Stelle einen biostimulierenden Effekt auszulösen, während das Gerät der Haut vorgehalten ist, welche Strahlungsquellen (166, 182, 188, 195) so betreibbar sind, dass sie Wellenlängen liefern, die so gewählt sind, dass sie in Bezug aufeinander synergetisch wirken, und welche Strahlungsquellen wenigstens eine Diode enthalten, die eine erste der Strahlungsquellen bildet und eine Wellenlänge gleich oder grösser als 650 nm und kleiner als 800 nm aufweist, und wenigstens eine Diode enthalten, die eine zweite der Strahlungsquellen bildet und eine Wellenlänge gleich oder grösser als 800 nm und kleiner als oder gleich 1500 nm aufweist.
2. Als Einheit ausgebildetes Gerät zur Biostimulation von Gewebe, mit einer Anordnung von Strahlungsquellen, die im wesentlichen in einer Ebene in festen Abständen voneinander angeordnet sind, wobei jede dieser Quellen aus einer im wesentlichen monochromatischen Strahlungsquelle besteht, die zum Liefern von sichtbarer oder infraroter Strahlung einer vorbestimmten Wellenlänge ausgewählt ist, wobei die Quellen in einer Einheit montiert sind, die in einer Beziehung zum Gewebe zu positionieren ist, und wobei wenigstens zwei dieser Quellen so ausgewählt und angeordnet sind, dass sie unterschiedliche Wellenlängen mit genügender Intensität liefern, um in die Haut eines Patienten an voneinander getrennten Stellen einzudringen und dabei an einer subkutanen Stelle mit genügend Leistung zu konvergieren, um an dieser Stelle einen biostimulierenden Effekt auszulösen, während das Gerät der Haut vorgehalten ist, welche Strahlungsquellen (166, 182, 188, 195) so betreibbar sind, dass sie Wellenlängen liefern, die so gewählt sind, dass sie in Bezug aufeinander synergetisch wirken, und welche Strahlungsquellen wenigstens eine Strahlungsquelle enthalten, die eine erste kleiner als 830 nm Wellenlänge liefert, wenigstens eine Strahlungsquelle enthalten, die eine zweite Wellenlänge grösser als oder gleich 830 nm und kleiner als 900 nm liefert, und wenigstens eine Strahlungsquelle enthalten, die eine dritte Wellenlänge gleich oder grösser als 900 nm liefert.
3. Gerät zur Biostimulation von Gewebe nach Anspruch 2, dadurch gekennzeichnet, dass
  - (a) die Strahlungsquellen ausgewählt sind aus der Gruppe bestehend aus superleuchtenden Dioden und Laserdioden und/oder
  - (b) die erste Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm und 820 nm,
  - 40 (c) die zweite Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 830 nm, 840 nm, 850 nm, 860 nm, 870 nm und 880 nm und
  - 45 (d) die dritte Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm und 1500 nm und/oder
  - (e) die erste Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 660 nm und 820 nm,
  - 50 (f) die zweite Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 875 nm und 880 nm und
  - 55 (g) die dritte Wellenlänge gleich 950 nm ist.
4. Gerät zur Biostimulation von Gewebe nach Anspruch 3, dadurch gekennzeichnet, dass die Strahlungsquellen mit Impulsfrequenzen moduliert sind, die aus dem Bereich von 2,28 Hz bis 400 kHz ausgewählt sind.
5. Gerät zur Biostimulation von Gewebe nach Anspruch 4, dadurch gekennzeichnet, dass die Impulsfrequenzen ausgewählt sind aus der Gruppe bestehend aus 2,28 Hz, 4,56 Hz, 9,12 Hz, 16 Hz, 18,24 Hz, 36,48 Hz, 73 Hz, 146 Hz, 292 Hz, 700 Hz, 1000 Hz, 5 kHz und 300 kHz.
6. Gerät zur Biostimulation von Gewebe nach Anspruch 3, 4 oder 5, dadurch gekennzeichnet, dass die genannte Anordnung folgendes enthält:
  - fünf superleuchtende 660 nm-Dioden (166),

EP 0 320 080 B1

eine 820 nm-Laserdiode (182),  
zehn superleuchtende 880 nm-Dioden oder 880 nm-Laserdioden (188) und  
fünf superleuchtende 950 nm-Dioden (195).

- 5 7. Gerät zur Biostimulation von Gewebe nach Anspruch 6, dadurch gekennzeichnet, dass  
die 820 nm-Diode (182) sich in der Mitte der Anordnung befindet,  
die 880 nm-Dioden (188) auf dem Umfang eines Kreises mit 10,5 mm Radius um die Mitte der  
Anordnung gleichmässig verteilt sind und  
die 660 nm-Dioden (166) und die 950 nm-Dioden (195) abwechselnd und in gleichen Abständen  
10 auf dem Umfang eines Kreises mit 17 mm Radius um die Mitte der Anordnung so verteilt sind, dass  
eine radiale Linie von der Mitte der Anordnung zu jeder der 660 nm-Dioden und jeder der 950 nm-  
Dioden den Bogen zwischen zwei der 880 nm-Dioden halbiert.
- 15 8. Gerät zur Biostimulation von Gewebe nach Anspruch 7, dadurch gekennzeichnet, dass  
die 820 nm-Diode (182) sich in der Mitte der Anordnung befindet,  
fünf der 880 nm-Dioden (188) auf dem Umfang eines Kreises mit 10,5 mm Radius um die Mitte der  
Anordnung gleichmässig verteilt sind,  
die 660 nm-Dioden (166) auf dem Umfang eines Kreises mit 17 mm Radius um die Mitte der  
Anordnung gleichmässig so verteilt sind, dass eine radiale Linie von der Mitte der Anordnung zu jeder  
20 der 660 nm-Dioden den Bogen zwischen zwei der 880 nm-Dioden im erwähnten ersten Satz halbiert,  
die 950 nm-Dioden (195) auf dem Umfang eines Kreises mit 17 mm Radius um die Mitte der  
Anordnung gleichmässig so verteilt sind, dass eine radiale Linie von der Mitte der Anordnung zu jeder  
der 950 nm-Dioden durch die Mitte einer der 880 nm-Dioden im erwähnten ersten Satz geht, und  
die restlichen fünf der 880 nm-Dioden (188) auf dem Umfang eines Kreises mit 27 mm Radius um  
25 die Mitte der Anordnung gleichmässig so verteilt sind, dass eine radiale Linie von der Mitte der  
Anordnung zu jeder dieser 880 nm-Dioden durch die Mitte einer der 660 nm-Dioden geht.
9. Gerät zur Biostimulation von Gewebe nach Anspruch 3, dadurch gekennzeichnet, dass die genannte  
Anordnung folgendes enthält:  
30 zehn superleuchtende 660 nm-Dioden (166),  
eine 820 nm-Laserdiode (182),  
zehn superleuchtende 880 nm-Dioden oder 880 nm-Laserdioden (188) und  
zehn superleuchtende 950 nm-Dioden (195).
- 35 10. Gerät zur Biostimulation von Gewebe nach Anspruch 9, dadurch gekennzeichnet, dass  
die 820 nm-Diode (182) sich in der Mitte der Anordnung befindet,  
die 880 nm-Dioden (188) auf dem Umfang eines Kreises mit 9,5 mm Radius um die Mitte der  
Anordnung gleichmässig verteilt sind,  
die 660 nm-Dioden (166) auf dem Umfang eines Kreises mit 18 mm Radius um die Mitte der  
40 Anordnung so verteilt sind, dass eine radiale Linie von der Mitte der Anordnung zu jeder der 660 nm-  
Dioden den Bogen zwischen zwei der 880 nm-Dioden halbiert, und  
die 950 nm-Dioden (195) auf dem Umfang eines Kreises mit 27 mm Radius um die Mitte der  
Anordnung gleichmässig so verteilt sind, dass eine radiale Linie von der Mitte der Anordnung zu jeder  
der 950 nm-Dioden durch die Mitte einer der 880 nm-Dioden geht.
- 45 11. Gerät zur Biostimulation von Gewebe nach Anspruch 1, dadurch gekennzeichnet, dass die Strahlungs-  
quellen folgendes enthalten:  
wenigstens eine Strahlungsquelle, die eine erste Wellenlänge kleiner als 830 nm liefert,  
wenigstens eine Strahlungsquelle, die eine zweite Wellenlänge grösser als oder gleich 830 nm und  
50 kleiner als 875 nm liefert,  
wenigstens eine Strahlungsquelle, die eine dritte Wellenlänge grösser als oder gleich 875 nm und  
kleiner als 900 nm liefert, und  
wenigstens eine Strahlungsquelle, die eine vierte Wellenlänge grösser als oder gleich 900 nm  
liefert.
- 55 12. Gerät zur Biostimulation von Gewebe nach Anspruch 11, dadurch gekennzeichnet, dass die Strahlungs-  
quellen ausgewählt sind aus der Gruppe bestehend aus superleuchtenden Dioden und Laserdioden.

13. Gerät zur Biostimulation von Gewebe nach Anspruch 12, dadurch gekennzeichnet, dass
  - die erste Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm und 820 nm,
  - die zweite Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 830 nm, 840 nm, 850 nm, 860 nm und 870 nm,
  - die dritte Wellenlänge gleich 880 nm ist und
  - die vierte Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 900 nm, 904 nm, 950 nm, 110 nm, 1300 nm und 1500 nm.
14. Gerät zur Biostimulation von Gewebe nach Anspruch 1, dadurch gekennzeichnet, dass die Strahlungsquellen folgendes enthalten:
  - wenigstens eine Diode, die eine erste Wellenlänge kleiner als 800 nm liefert, und
  - wenigstens eine Diode, die eine zweite Wellenlänge grösser als oder gleich 800 nm liefert.
15. Gerät zur Biostimulation von Gewebe nach Anspruch 14, dadurch gekennzeichnet, dass
  - die erste Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 650 nm, 660 nm, 680 nm, 750 nm und 780 nm und
  - die zweite Wellenlänge ausgewählt ist aus der Gruppe bestehend aus 800 nm, 810 nm, 820 nm, 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, 880 nm, 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm und 1500 nm.
16. Gerät nach Anspruch 1, dadurch gekennzeichnet, dass die Strahlungsquellen (166, 182, 188, 195) so gewählt sind, dass sie in der genannten Ebene eine mittlere Leistungsdichte von wenigstens 10 mW/cm<sup>2</sup> aussenden.
17. Gerät nach Anspruch 1, dadurch gekennzeichnet, dass die Strahlungsquellen (166, 182, 188, 195) so gewählt sind, dass sie an einer Stelle auf der Oberfläche der Haut des Patienten eine Leistungsdichte von wenigstens 120 mW/cm<sup>2</sup> liefern.
18. Gerät nach Anspruch 1, dadurch gekennzeichnet, dass es folgendes enthält:
  - (a) Leistungsliefermittel (40) und mit diesen Leistungsliefermitteln in Verbindung stehende Mittel (47, 45) zum Modulieren der Ausgangsleistung der genannten Quellen mit Impulsen und Variieren der Modulationsimpulsfrequenz der Strahlungsquellen und/oder
  - (b) mit den Leistungsliefermitteln in Verbindung stehende Mittel (45) zum Variieren der Impulsdauer der Strahlungsquellen und/oder
  - (c) mit den Leistungsliefermitteln in Verbindung stehende Mittel (72, 70) zum Festlegen des Zeitintervalls, in welchem Leistung an die Strahlungsquellen geliefert wird, und/oder
  - (d) mit den Leistungsliefermitteln (75, 70) in Verbindung stehende Mittel zum Messen der elektrischen Leitfähigkeit des genannten Gewebes und/oder
  - (e) mit der genannten Anordnung in Verbindung stehende Mittel (42) zum Messen der optischen Leistung, die von den Strahlungsquellen ausgesandt wird, und/oder
  - (f) mit einer Strahlsteuereinheit in Verbindung stehende Mittel (50) zum Feststellen von Strahlung von den Strahlungsquellen und mit den Mitteln zum Feststellen verbundene Anzeigemittel (71) zum Anzeigen der Tatsache, dass Strahlung von den Strahlungsquellen ausgesandt wird.

#### Revendications

1. Dispositif unitaire pour la stimulation biologique de tissus, comprenant un arrangement de sources de rayonnement monté dans un plan en substance plat (80, 90, 100) à des distances fixes l'une de l'autre, chaque source étant constituée d'une source de rayonnement en substance monochromatique choisie pour fournir un rayonnement visible ou infrarouge d'une longueur d'onde choisie, les sources étant montées dans une unité destinée à être positionnée par rapport aux tissus, et au moins deux de ces sources étant choisies et positionnées pour fournir des longueurs d'onde différentes d'intensité suffisante pour pénétrer la peau d'un patient en des endroits séparés tout en convergeant vers un point sous-cutané avec une puissance suffisante pour déclencher un effet de stimulation biologique en ce point pendant que le dispositif est présenté à la peau, les sources de rayonnement (166, 182, 188, 195) pouvant être mises en œuvre pour fournir des longueurs d'onde choisies synergiques l'une par rapport à l'autre et comprenant au moins une diode qui fournit une première source de rayonnement ayant une

longueur d'onde égale ou supérieure à 650 nm et inférieure à 800 nm et au moins une diode qui fournit une seconde source de rayonnement ayant une longueur d'onde supérieure ou égale à 800 nm et inférieure ou égale à 1500 nm.

- 5 2. Dispositif unitaire pour la stimulation biologique de tissus, comprenant un arrangement de sources de rayonnement monté dans un plan en substance plat à des distances fixes l'une de l'autre, chaque source comprenant une source de rayonnement en substance monochromatique choisie pour fournir un rayonnement visible ou infrarouge d'une longueur d'onde choisie, les sources étant montées dans une unité destinée à être positionnée par rapport aux tissus, et au moins deux de ces sources étant choisies et positionnées pour fournir des longueurs d'onde différentes d'intensité suffisante pour pénétrer la peau du patient en des endroits séparés tout en convergeant vers un point sous-cutané avec une puissance suffisante pour déclencher un effet de stimulation biologique en ce point pendant que le dispositif est présenté à la peau, les sources de rayonnement (166, 182, 188, 195) pouvant être mises en oeuvre pour fournir des longueurs d'onde choisies synergiques l'une par rapport à l'autre et comprenant au moins une source de rayonnement qui fournit une première longueur d'onde inférieure à 830 nm, au moins une source de rayonnement qui fournit une deuxième longueur d'onde supérieure ou égale à 830 nm et inférieure à 900 nm et au moins une source de rayonnement qui fournit une troisième longueur d'onde supérieure ou égale à 900 nm.
- 20 3. Dispositif pour la stimulation biologique de tissus suivant la revendication 2, caractérisé en ce que :
  - (a) les sources de rayonnement sont choisies dans le groupe comprenant les diodes superlumineuses et les diodes laser, et/ou
  - (b) la première longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm et 820 nm;
  - 25 la deuxième longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 830 nm, 840 nm, 850 nm, 860 nm, 870 nm et 880 nm, et
  - la troisième longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm et 1500 nm, et/ou
  - 30 (c) la première longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 660 nm et 820 nm;
  - la deuxième longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 875 nm et 880 nm, et
  - la troisième longueur d'onde est de 950 nm.
- 35 4. Dispositif pour la stimulation biologique de tissus suivant la revendication 3, caractérisé en ce que les sources de rayonnement sont modulées à des fréquences d'impulsions choisies dans la gamme de 2,28 Hz à 400 kHz.
- 40 5. Dispositif pour la stimulation biologique de tissus suivant la revendication 4, caractérisé en ce que les fréquences d'impulsions sont choisies dans le groupe comprenant des fréquences de 2,28 Hz, 4,56 Hz, 9,12 Hz, 16 Hz, 18,24 Hz, 36,48 Hz, 73 Hz, 146 Hz, 292 Hz, 700 Hz, 1000 Hz, 5 kHz et 300 kHz.
- 45 6. Dispositif pour la stimulation biologique de tissus suivant la revendication 3, 4 ou 5, caractérisé en ce que l'arrangement comprend :
  - cinq diodes superlumineuses de 660 nm (166);
  - une diode laser de 820 nm (182);
  - dix diodes superlumineuses ou laser de 880 nm (188), et
  - cinq diodes superlumineuses de 950 nm (195).
- 50 7. Dispositif pour la stimulation biologique de tissus suivant la revendication 6, caractérisé en ce que :
  - la diode de 820 nm (182) est positionnée au centre de l'arrangement;
  - les diodes de 880 nm (188) sont réparties de manière égale autour de la circonference d'un cercle de 10,5 mm de rayon à partir du centre de l'arrangement, et
  - 55 les diodes de 660 nm (166) et de 950 nm (195) sont réparties en alternance et également espacées autour de la circonference d'un cercle de 17 mm de rayon à partir du centre de l'arrangement, de sorte qu'une ligne radiale allant du centre de l'arrangement à chacune des diodes de 660 nm ou de 950 nm bissecte l'arc entre deux des diodes de 880 nm.

8. Dispositif pour la stimulation biologique de tissus suivant la revendication 7, caractérisé en ce que :
  - la diode de 820 nm (182) est positionnée au centre de l'arrangement;
  - cinq des diodes de 880 nm (188) sont également réparties autour de la circonférence d'un cercle de 10,5 mm de rayon à partir du centre de l'arrangement;
  - les diodes de 660 nm (166) sont réparties de manière égale autour de la circonférence d'un cercle de 17 mm de rayon à partir du centre de l'arrangement, de sorte qu'une ligne radiale allant du centre de l'arrangement jusqu'à chacune des diodes de 660 nm bissecte l'arc entre deux des diodes de 880 nm du premier jeu;
  - les diodes de 950 nm (195) sont réparties de manière égale autour de la circonférence d'un cercle de 17 mm de rayon à partir du centre de l'arrangement, de sorte qu'une ligne radiale allant du centre de l'arrangement jusqu'à chacune des diodes de 950 nm passe par le centre d'une des diodes de 880 nm du premier jeu, et
  - les cinq diodes de 880 nm (188) restantes sont réparties de manière égale autour de la circonférence d'un cercle de 27 mm de rayon à partir du centre de l'arrangement, de sorte qu'une ligne radiale allant du centre de l'arrangement jusqu'à chacune des diodes de 880 nm passe par le centre d'une des diodes de 660 nm.
9. Dispositif pour la stimulation biologique de tissus suivant la revendication 3, caractérisé en ce que l'arrangement comprend :
  - dix diodes superlumineuses de 660 nm (166);
  - une diode laser de 820 nm (182);
  - dix diodes superlumineuses ou laser de 880 nm (188), et
  - dix diodes superlumineuses de 950 nm (195).
10. Dispositif pour la stimulation biologique de tissus suivant la revendication 9, caractérisé en ce que :
  - la diode de 820 nm (182) est placée au centre de l'arrangement;
  - les diodes de 880 nm (188) sont réparties de manière égale autour de la circonférence d'un cercle de 9,5 mm de rayon à partir du centre de l'arrangement;
  - les diodes de 660 nm (166) sont réparties de manière égale autour de la circonférence d'un cercle de 18 mm de rayon à partir du centre de l'arrangement, de sorte qu'une ligne radiale allant du centre de l'arrangement jusqu'à chacune des diodes de 660 nm bissecte l'arc entre deux des diodes de 880 nm, et
  - les diodes de 950 nm (195) sont réparties de manière égale autour de la circonférence d'un cercle de 27 mm de rayon à partir du centre de l'arrangement, de sorte qu'une ligne radiale allant du centre de l'arrangement jusqu'à chacune des diodes de 950 nm passe par le centre d'une des diodes de 880 nm.
11. Dispositif pour la stimulation biologique de tissus suivant la revendication 1, caractérisé en ce que les sources de rayonnement comprennent :
  - au moins une source de rayonnement fournissant une première longueur d'onde inférieure à 830 nm;
  - au moins une source de rayonnement fournissant une deuxième longueur d'onde supérieure ou égale à 830 nm et inférieure à 875 nm;
  - au moins une source de rayonnement fournissant une troisième longueur d'onde supérieure ou égale à 875 nm et inférieure à 900 nm, et
  - au moins une source de rayonnement fournissant une quatrième longueur d'onde supérieure ou égale à 900 nm.
12. Dispositif pour la stimulation biologique de tissus suivant la revendication 11, dans lequel les sources de rayonnement sont choisies dans le groupe comprenant les diodes superlumineuses et les diodes laser.
13. Dispositif pour la stimulation biologique de tissus suivant la revendication 12, caractérisé en ce que :
  - la première longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm et 820 nm;
  - la deuxième longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 830 nm, 840 nm, 850 nm, 860 nm et 870 nm;
  - la troisième longueur d'onde est de 880 nm, et

**EP 0 320 080 B1**

la quatrième longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 900 nm, 904 nm, 950 nm, 110 nm, 1300 nm et 1500 nm.

14. Dispositif pour la stimulation biologique de tissus suivant la revendication 1, caractérisé en ce que les sources de rayonnement comprennent :

5 au moins une diode fournissant une première longueur d'onde inférieure à 800 nm, et au moins une diode fournissant une deuxième longueur d'onde supérieure ou égale à 800 nm.

15. Dispositif pour la stimulation biologique de tissus suivant la revendication 14, caractérisé en ce que :

10 la première longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 650 nm, 660 nm, 680 nm, 750 nm et 780 nm, et la deuxième longueur d'onde est choisie dans le groupe comprenant des longueurs d'onde de 800 nm, 810 nm, 820 nm, 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, 880 nm, 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm et 1500 nm.

16. Dispositif suivant la revendication 1, caractérisé en ce que les sources de rayonnement (166, 182, 188, 195) sont choisies de manière à émettre une densité de puissance moyenne au niveau dudit plan d'au moins 10 mW/cm<sup>2</sup>.

17. Dispositif suivant la revendication 1, caractérisé en ce que les sources de rayonnement (166, 182, 188, 195) sont choisies de manière à fournir une densité de puissance d'au moins 120 mW/cm<sup>2</sup> en un point déterminé sur la surface de la peau du patient.

18. Dispositif suivant la revendication 1, caractérisé en ce qu'il est pourvu de :

25 (a) une alimentation de courant (40) et des moyens (47, 45) en communication avec l'alimentation de courant pour moduler la sortie des sources au moyen d'impulsions et pour faire varier la fréquence d'impulsions de modulation des sources de rayonnement, et/ou

(b) un moyen (45) en communication avec l'alimentation de courant pour faire varier la durée des impulsions des sources de rayonnement, et/ou

30 (c) des moyens (72, 70) en communication avec l'alimentation de courant pour minuter la période pendant laquelle du courant est fourni aux sources de rayonnement, et/ou

(d) un moyen en communication avec l'alimentation de courant (75, 70) pour mesurer la conductivité électrique des tissus, et/ou

(e) un moyen (42) en communication avec l'arrangement pour mesurer la puissance optique émise par les sources de rayonnement, et/ou

35 (f) un moyen (50) en communication avec une unité de commande de faisceau pour détecter le rayonnement provenant des sources de rayonnement, et

un moyen indicateur (71) connecté au moyen de détection pour indiquer que du rayonnement est émis par les sources de rayonnement.

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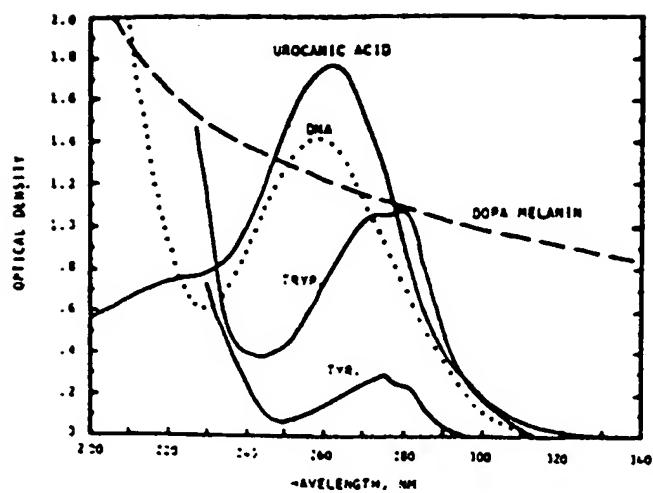


FIG. 1

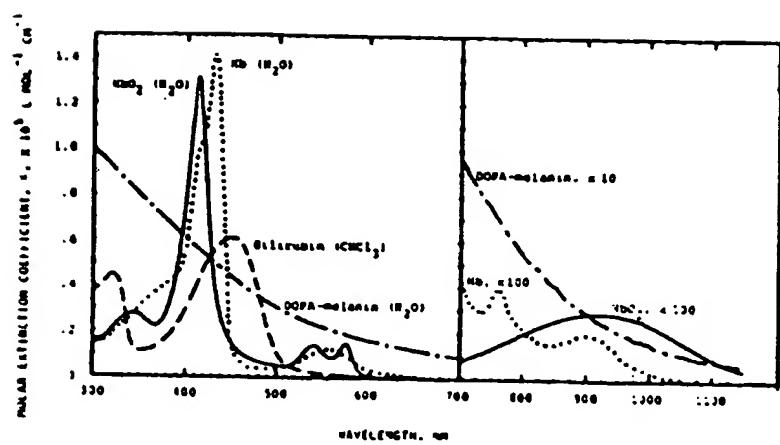


FIG. 2

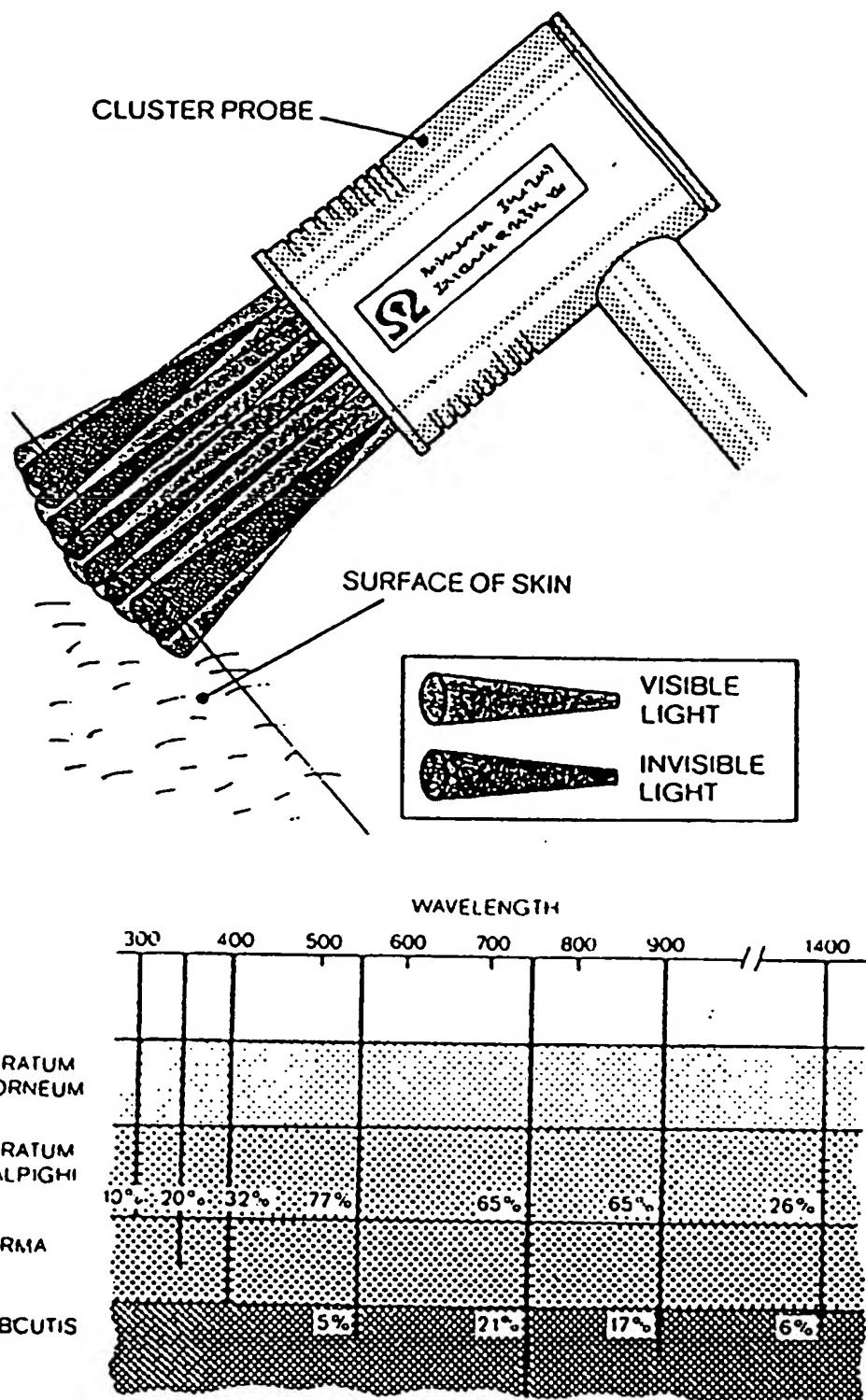


FIG. 3

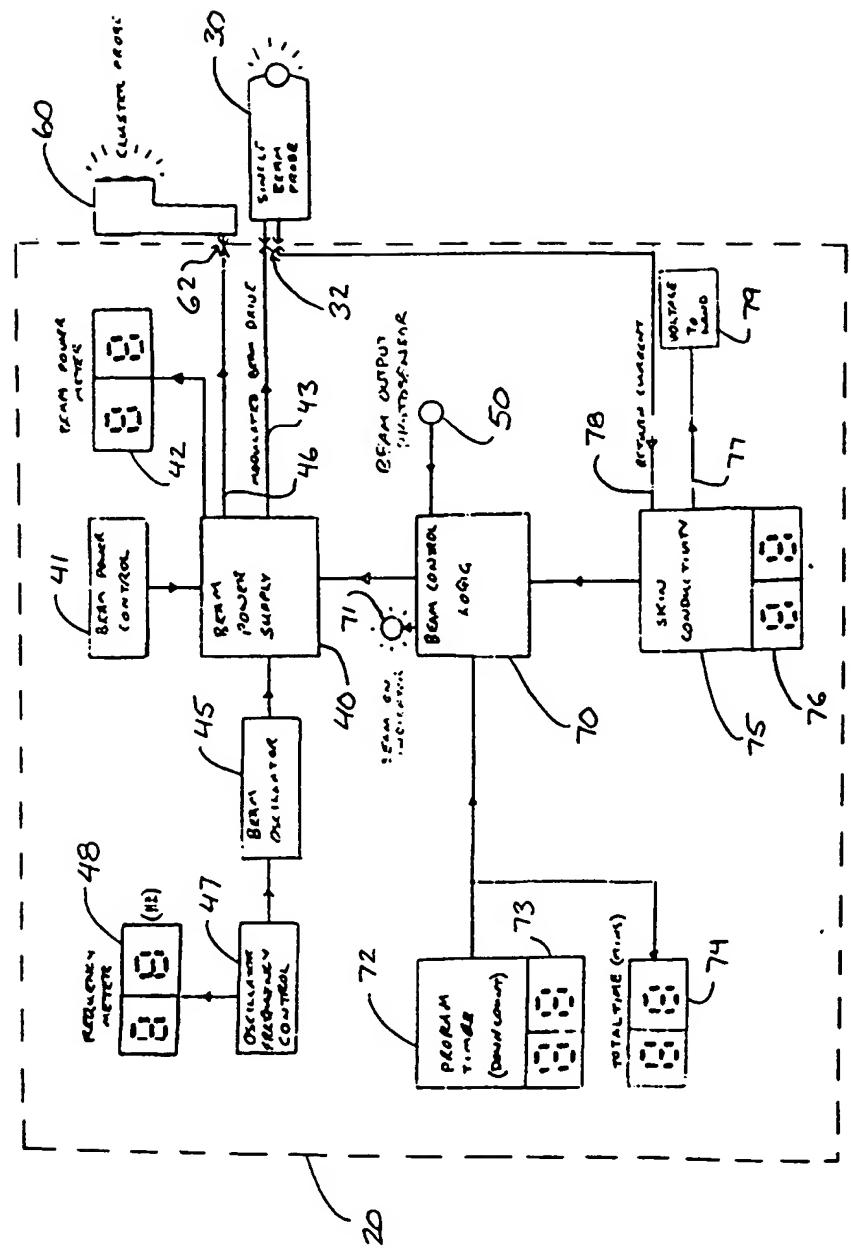


FIG. 4

EP 0 320 080 B1

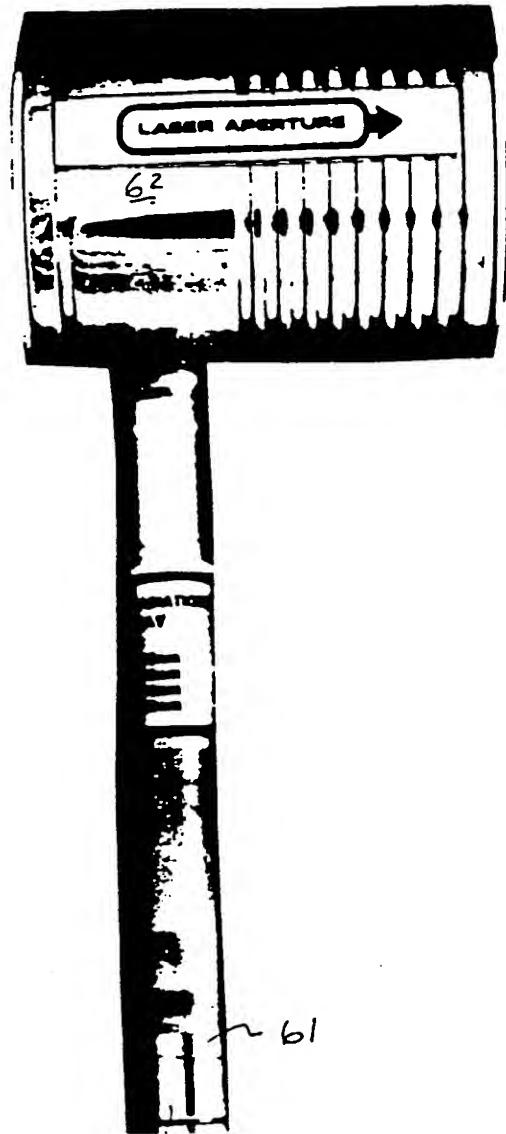


FIG. 5

EP 0 320 080 B1

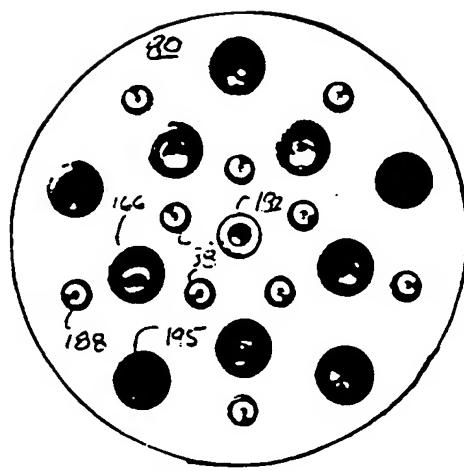


FIG. 6

EP 0 320 080 B1

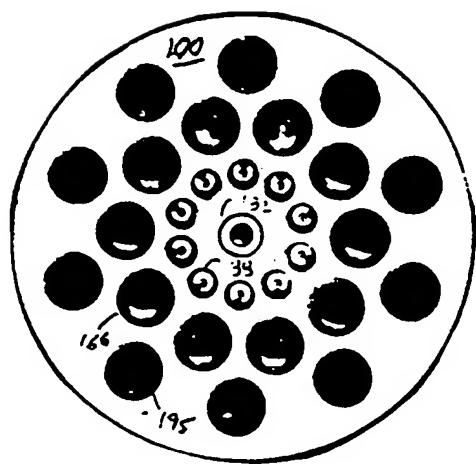


FIG. 8

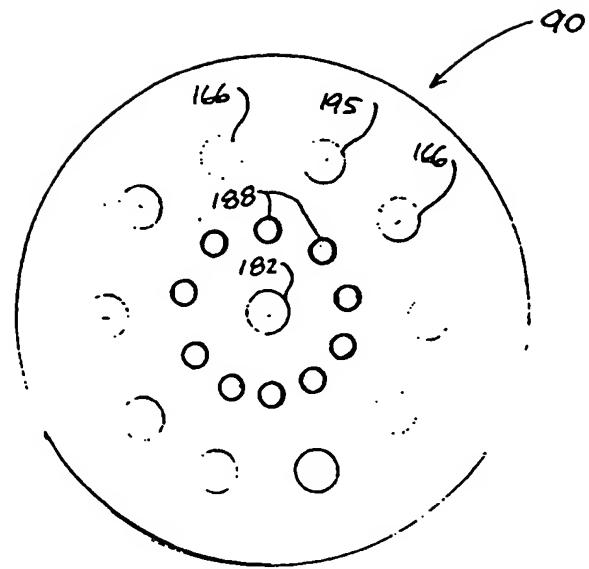


FIG. 7

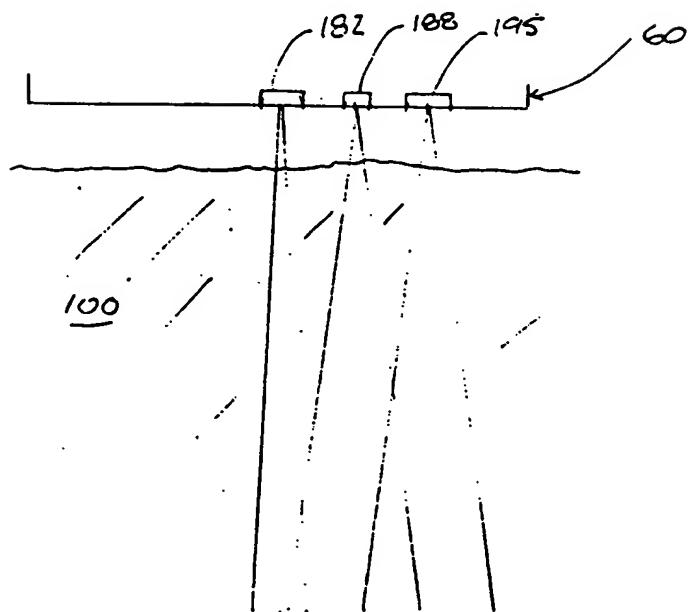


FIG. 9

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